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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/748,038	12/22/2000	James J. Benedict	2103.013900	4147
45488	7590	12/16/2004	EXAMINER	
WILLIAMS, MORGAN & AMERSON, P.C./ZIMMER			RUSSEL, JEFFREY E	
10333 RICHMOND, SUITE 1100				
HOUSTON, TX 77042			ART UNIT	PAPER NUMBER

1654

DATE MAILED: 12/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/748,038

Applicant(s)

BENEDICT ET AL.

Examiner

Jeffrey E. Russel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 11, 18-21 and 28-30 is/are allowed.
- 6) ☒ Claim(s) 2-7, 12-17, 22-27 and 31 is/are rejected.
- 7) ☒ Claim(s) 1, 8-10 and 32 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 November 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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1. The disclosure is objected to because of the following informalities: The specification at page 10, line 8, and at page 11, line 26, refers to a Figure 19D which no longer exists in this application. Appropriate correction is required.
2. Claims 1-10 are objected to because of the following informalities: At claim 1, line 2; claim 8, line 2; and claim 9, line 2; "blow" should be changed to "blood". Appropriate correction is required.
3. The effective filing date of instant claims 1, 11, 21, and 32 is deemed to be October 16, 1998, the filing date of parent application 09/173,989. Instant claims 1, 11, 21, and 32 are deemed to be entitled under 35 U.S.C. 120 to the benefit of the filing date of parent application 09/173,989 because the parent application '989, under the test of 35 U.S.C. 112, first paragraph discloses the claimed invention. Accordingly, Ripamonti et al (U.S. Patent Application Publication 2003/0104977) is not prior art against these claims.

The effective filing date of instant claims 2-10, 12-20, and 22-31 is deemed to be December 22, 2000, the filing date of the instant application. Instant claims 2-10, 12-20, and 22-31 are not deemed to be entitled under 35 U.S.C. 120 to the benefit of the filing date of parent application 09/173,989 because the parent application '989, under the test of 35 U.S.C. 112, first paragraph does not disclose a mixture of proteins which comprises at least two growth factors selected from those listed in instant claims 2, 12, and 22; does not disclose administration to a human; does not disclose subcutaneous, intramuscular, or intravenous administration; does not disclose discrete or continuous administration; does not disclose administration in combination with a preservative or an adjuvant; does not disclose a mixture of proteins which comprises those specified in instant claims 8, 18, and 28; does not disclose obtaining the protein mixture by steps

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including cleaning ground bone, demineralizing cleaned ground bone, and extracting with protein denaturants in general; and does not disclose mammalian bone in general. Accordingly, because U.S. Patent No. 6,211,157 has an earlier effective filing date than these claims and has a different inventive entity than these claims, U.S. Patent No. 6,211,157 is available as prior art against these claims under 35 U.S.C. 102(e). Also, Ripamonti et al (U.S. Patent Application Publication 2003/0104977) is prior art against these claims.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 2, 12, 22, and 31 are rejected under 35 U.S.C. 102(e) as being anticipated by Ripamonti et al (U.S. Patent Application Publication 2003/0104977). Ripamonti et al teach inducing angiogenesis in mammals by administering a combination of a morphogenic protein and a morphogenic protein stimulator factor. Examples of situations where angiogenesis is required include wound healing, bone repair, ischemic heart disease, and ischemic peripheral vascular disease. The morphogenic protein can be BMP-3, BMP-4, BMP-5, BMP-6, and BMP-7, and the morphogenic protein stimulatory factor can be TGF- β 1, bFGF, IGF-1, EGF, HGF, and TGF- α . See, e.g., the Abstract; paragraph [0003]; Examples 5 and 6; and claims 1, 6, 11, and 13-16. The above-listed morphogenic proteins and morphogenic protein stimulator factors, being identical to those specified in instant claims 2, 12, and 22, are inherently derivable from ground mammalian bone. This rejection assumes that Applicants' claim limitation "derived from ground bone" is a product-by-process limitation which functionally limits the types of proteins embraced by Applicants' claims, and does not constitute a positive process step which must be practiced in combination with the administering step.

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6. Claims 3-7, 13-17, and 23-27 are rejected under 35 U.S.C. 103(a) as being obvious over Ripamonti et al (U.S. Patent Application Publication 2003/0104977). Application of Ripamonti et al is the same as in the above rejection of claims 2, 12, 22, and 31. Ripamonti et al do not teach administration to a human, do not teach administering subcutaneously, intramuscularly, or intravenously, and do not teach administering discretely or continuously. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to induce angiogenesis in humans in the method of Ripamonti et al because Ripamonti et al is not limited to the treatment of any particular patient and because human patients are the most common type of patients in need of angiogenesis. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to administer the active agents of Ripamonti et al subcutaneously, intramuscularly, intravenously, discretely, or continuously, because these are known methods of administration and known dosage schedules in the pharmaceutical arts and it is routine in the pharmaceutical arts to determine all effective and optimal methods of administration and dosage schedules.

7. Applicant's arguments filed November 17, 2004 have been fully considered but they are not persuasive.

The terminal disclaimer filed November 17, 2004 has been approved.

The rejections over Ripamonti et al (U.S. Patent Application Publication 2003/0104977) are maintained because the affidavit or declaration under 37 CFR 1.131 discussed in Applicants' response has not yet been received. The examiner will enter and consider any such declaration as long as it is filed before the filing of an appeal brief.

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8. Claims 11, 18-21, and 28-30 are allowed. Claims 1 and 8-10 would be allowable if rewritten or amended to overcome the claim objections set forth in this Office action. Claim 32 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

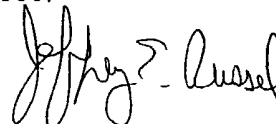
Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Bruce Campell can be reached at (571) 272-0974. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel

Primary Patent Examiner

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JRussel

December 15, 2004